



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/566,927

09/13/2006

Stephen Martone

386/05062

1141

44909

7590

02/09/2011

PRTSI

P.O. Box 16446

Arlington, VA 22215

EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT

PAPER NUMBER

3779

MAIL DATE

DELIVERY MODE

02/09/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,927	Applicant(s) MARTONE ET AL.	
	Examiner MATTHEW J. KASZTEJNA	Art Unit 3779	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43,48-50,73-76,79-90,92 and 94-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43,48-50,73-76,79-90,92 and 94-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/3/11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on January 26, 2011, amended claim 1 is acknowledged. The following new grounds of rejection are set forth:

Claim Objections

Claim 92 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim fails to further limit independent claim 43 from which it is depend with the current language "the external sheath extends over at least 50% of the internal sheath". As per the telephonic interview, newly added language "circumferentially surrounding" read in view of the specification is to mean that the external sheath *completely* surrounds the internal sheath. Thus, claim 92 fails to further limit claim 43.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43, 48-50, 73-76, 79, 81-84, 86-89, 92 and 94-97 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,201,908 to Jones.

In regard to claim 43, Jones discloses a sheath assembly 30 for a probe, comprising: an internal sheath 37 configured to isolate a probe 16 from body fluids; and an external sheath 36 circumferentially surrounding the internal sheath (see Figs. 7-8), the external sheath configured to define a channel for passing fluids, tools or working tubes and the internal and external sheaths being connected to each other (via cap 40, see Figs. 2-6 and Col. 4, Lines 38-67), wherein the external sheath and the internal sheath are not coupled along their length (see Col. 5, Lines 25-42), and wherein the internal sheath is not affected when tools or working tubes are passed through the channel (see Figs. 1-2).

In regard to claims 48 and 96, Jones discloses a sheath assembly for a probe, wherein the internal and external sheaths are connected substantially only at a plurality of circumferential points at a distal end of the external sheath (see Figs. 5-6). The internal and external sheaths are connected to one another via cap 40 which sealing engages each of the access channels and sheath to one another. Figure 8 clearly shows that the access channels 60a-c, endoscope channel 37 and external sheath 36 are clearly not coupled along a length thereof and are simply connected to one another via cap 40.

In regard to claim 49, Jones discloses a sheath assembly for a probe wherein the internal and external sheaths coextend at their distal ends, such that their distal ends extend to a same point (Figs. 4-5).

In regard to claim 50, in an alternate interpretation of the cited reference, Jones discloses a sheath assembly 30 for a probe, comprising: an internal sheath 60c configured to isolate a probe 66 from body fluids; and an external sheath 36 circumferentially surrounding the internal sheath (see Figs. 7-8), the external sheath configured to define a channel for passing fluids, tools or working tubes and the internal and external sheaths being connected to each other (via cap 40, see Figs. 2-6 and Col. 4, Lines 38-67), wherein the external sheath and the internal sheath are not coupled along their length (see Col. 5, Lines 25-42), and wherein the internal sheath is not affected when tools or working tubes are passed through the channel (see Figs. 1-2) and wherein the internal extends beyond the distal end of the external sheath (Figs. 2-3 and Col. 6, Line 9-20).

In regard to claim 73, Jones discloses a sheath assembly for a probe wherein at least one channel 60a-c is defined between the external sheath and the internal sheath along at least a portion of the sheath assembly (Fig. 8).

In regard to claim 74, Jones discloses a sheath assembly for a probe wherein at least one channel 60c is open at the distal end of the sheaths (see Fig. 2 and Col. 6, Lines 1-8).

In regard to claim 75, Jones discloses a sheath assembly for a probe wherein the channel does not surround the entire internal sheath (Figs. 7-8).

In regard to claim 76, Jones discloses a sheath assembly for a probe wherein there are two channels 60a-c (see Figs. 7-8 and Col. 5, Lines 15-25).

Art Unit: 3779

In regard to claim 79, Jones discloses a sheath assembly for a probe wherein the external sheath and the internal sheath are connected to a proximal connector 34 (see Fig. 1 and Col. 3, Lines 32-67).

In regard to claim 81, Jones discloses a sheath assembly for a probe wherein the external sheath is sealed at its distal end via cap 40 (see Col. 4, Lines 40-67)

In regard to claim 82, Jones discloses a sheath assembly for a probe wherein the internal sheath comprises an imaging window 48 at its distal end (see Col. 4, Lines 28-38).

In regard to claims 83-84 and 86, Jones discloses a sheath assembly for a probe wherein the internal and external sheaths are foldable, bendable and/or stretchable (see Col. 4, Lines 8-17). The sheaths are fully capable of being bent, folded or stretched.

In regard to claim 87, Jones discloses a sheath assembly for a probe wherein a sheath assembly wherein the internal and external sheaths have *substantially* the same thickness (see Figs. 8).

In regard to claim 88, Jones discloses a sheath assembly for a probe wherein the internal and external sheaths are formed from the same material (see Col. 4, Lines 8-17).

In regard to claim 89, Jones discloses a sheath assembly for a probe wherein, a rigid pipe section 34 is located at the proximal end of the internal sheath (see Col. 3, Lines 63-67).

In regard to claim 92, Jones discloses a sheath assembly for a probe wherein, wherein the external sheath extends over at least 50% of the internal sheath (See Figs. 7-8).

In regard to claim 94, Jones discloses a sheath assembly for a probe wherein the internal sheath is bendable, configured to bend longitudinally around corners while the sheath assembly is inserted into a patient (see Fig. 1 and Col. 4, Lines 8-17).

In regard to claim 95, Jones discloses a sheath assembly for a probe wherein the external sheath is folded (i.e. rolled) (See Col. 6, Lines 35-43). In regard to the limitation “during insertion into the body”, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). If the prior art structure is capable of performing the intended use, then it meets the claim. Thus, the sheath is fully capable of being folded onto the endoscope as it is inserted into the body.

In regard to claim 97, Jones discloses a sheath assembly for a probe wherein the channel imparts an asymmetrical force on the internal sheath when tools or working tubes are passed through the channel (see Figs 7-8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 5,201,908 to Jones in view of U.S. Patent No 7,431,694 to Stefanchik et al.

In regard to claims 80, Jones discloses a sheath assembly for a probe (see rejection above) but is silent with respect to the external sheath is formed with an internal notch capable of receiving a dovetail of a working tube. Stefanchik et al. teach of an analogous endoscopic sheath comprising an attachment flange 25 for connecting rail 30 to endoscope 100. A sheath 80 surrounds endoscope 100 and rail 30. Rail 30 can be joined to an inner surface of sheath 80. Such an embodiment allows passage of mating member 40 and accessory 50 within sheath 80, providing for atraumatic passage along the tissue surface (see Fig. 6). It would have been obvious to one skilled in the art at the time the invention was made to provide an internal notch capable of receiving a dovetail of a working tube in the apparatus of Jones to provide an alternate means for inserting a working tube to a target site within the body as taught by Stefanchik et al.

Claim 85 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 5,201,908 to Jones in view of U.S. Patent No 7,431,694 to Stefanchik et al.

In regard to claims 85 and 90, Jones discloses a sheath assembly for a probe (see rejection above) but is silent with respect to the external sheath being non-collapsible and non-elastic. Bacich et al. teach of an analogous endoscopic sheath wherein the external sheath is non-elastic (Col. 14, lines 25-29). Furthermore, Bacich discloses that the external sheath is non- self collapsible (Col. 14, lines 8-12). It would

Art Unit: 3779

have been obvious to one skilled in the art at the time the invention was made to provide a non-collapsible external sheath in the apparatus of Jones to provide an alternate means allowing for easier and faster insertion of an instrument therethrough during a surgical procedure as taught by Stefanchik et al. It is well known in the art to provide both rigid and flexible endoscope shafts dependent upon the surgical procedure being performed. Additionally, Jones discloses the external sheath being made of rubber (see Col. 4, Lines 15-17). It is possible to construct a sheath from rubber that is non collapsible.

Response to Arguments

Applicant's arguments with respect to claims 43, 48-50, 73-76, 79-90, 92 and 94-97 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3779

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas J. Sweet can be reached on (571) 272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew J Kasztejna/
Primary Examiner, Art Unit 3779

2/4/11